EPO
Epidemiology Program Office
Issue 1

ADS Newsletter
Office of the Associate Director for Science
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ADS Newsletter: Inaugural Issue

The Office of the Associate Director for Science (OADS) plays an integral role in EPO scientific and programmatic activities. The OADS provides a wide range of support to EPO staff and assignees. Some of the functions of the OADS include the following:

- Advise EPO director and staff on science issues;
- Assess scientific misconduct;
- Conduct scientific ethics training;
- Manage EPO adherence to IRB;
- Clear manuscripts and other publications/presentations; and
- Collaborate/coordinate with other parts of CDC and outside organizations on science issues.

The OADS hopes to contribute to a better and more informed staff to meet ever-changing public health challenges. The OADS has developed this newsletter as part of the effort to enhance communication and information sharing. This periodic newsletter will update EPO staff on human subjects, IRB, ethics, policy, and other relevant issues.

The OADS appreciates your feedback and input. Please e-mail your comments and suggestions to Aun Lor (alor@cdc.gov).

INSIDE THIS ISSUE

Ethical Dilemmas in Public Health

Scenario 1 – A CDC investigator working with a state health department was involved in a study conducted in collaboration with investigators from the state. The state IRB; and CDC IRB originally approved the protocol; however, after study initiation there were some major changes to the study protocol. An amendment was submitted to the state IRB for approval, but approval from CDC for the amendment was not obtained before implementing the changes.

Issues – What IRB action should be taken? What are the investigator's responsibilities? How will this affect the study?

An investigator has a responsibility to inform the CDC IRB of any changes to the protocol, whether major or minor. This can be done through an amendment submitted through the CIO. Not informing the IRB of changes is considered scientific misconduct and IRB action is considered. The investigator could be removed from further participation in the study or other serious action taken. The study would be allowed to continue with state IRB oversight, but without the involvement of the CDC investigator.

Scenario 2 - Blood collection was taken for a specific purpose as stated in the consent form. After this was done, excess serum without identifiers remained.

Issues - Can the sera be used for other examinations that may or may not be related to the original study?

Legally and ethically, the answer is no, unless permission was obtained in the original consent to keep the serum for possible future uses. The serum does not belong to the investigator(s) and the investigator(s) must seek permission to use it. The serum should be destroyed, unless the consent specifically requested permission to keep it.

If you have ethical scenarios you would like to share, please submit them to Aun Lor (alor@cdc.gov).

EPO Publications Clearance Process

The purpose of formal scientific clearance is to ensure quality of science, to facilitate responsible advice to the public, and to avoid conflicting statements. Clearance is not intended to suppress or regulate creativity, cause an unnecessary delay in study publication, or replace normal review and revision activities that occur between colleagues and supervisors. Rather, clearance is the last opportunity for scientific, editorial, and policy review before the results of a scientific investigation or programmatic activity are submitted for publication. Clearance is ***mandatory*** for all written material that CDC employees author or co-author, whether published by CDC or outside CDC (see *EPO Overview of Scientific Procedures* for the list of materials requiring clearance).

All manuscripts and abstracts for presentation or publication must be cleared through the following:

1. Author's supervisor;
2. Author's Division Director or Director's designee (often Division ADS);
3. Office of Scientific and Health Communications (OSHC) for record keeping, editing, and Internet Clearance (as relevant) by the EPO Webmaster;
4. EPO/OD Associate Director for Science - for final clearance.

The Division Director is responsible for setting up a system for clearance within the division. Normally, this process includes a review by the author's supervisor and the Division Director or designee. Manuscripts sent for clearance should be those that the Division Director considers next-to-final drafts.

Authors should adhere to the following procedures for obtaining clearance:

- CDC Clearance forms (.576) must include initials (or e-mails) of all authors for approval, HSR and Scientific Ethics # if applicable, signature of Division Director or designee, and the accession number to each approval application.
- Send two *double-spaced*, single-sided copies of the draft manuscript to: Evelyn Duval, EPO's Office of Scientific and Health Communications (OSHC), Bldg. 1, Room 5428, MS C-08.
- After editing, OSHC will send the manuscript to the ADS, EPO, for approval. If the ADS approves the manuscript, OSHC will return it and a copy of the clearance form through the Division Director to the author. The manuscript can then be retyped and submitted to the publisher.

Working Groups to Improve Public Health Programs and Practices

The OADS is involved in several new initiatives at CDC. Two of these initiatives are coordinated by staff from EPO, the Health and Human Rights Workgroup, and the CDC-wide Social Determinants of Health (SDOH).

The EPO Health and Human Rights Workgroup

It is generally recognized that **health** is a **fundamental human right**, and that human rights are the social pre-conditions in which people can achieve an optimal state of health. However, this intrinsic link has often been overlooked, misunderstood, and sometimes undermined even by health officials. It is critical that those who work to protect the health of the public acknowledge and understand the important role that human rights play in securing and promoting health. Infringement on human rights has a detrimental impact on health; likewise poor health has a deteriorating effect on peoples' ability to secure their own fundamental human rights.

It is out of this concern that EPO initiated an internal working group on Health and Human Rights in July 2001 as part of an ongoing effort to improve public health practice. The workgroup's goal is to improve and protect the health of the public by incorporating a human rights framework into EPO program and research activities. The workgroup hopes to develop guidance on how to incorporate human rights into program activities.

Contact Aun Lor (alor@cdc.gov) for more information.

Social Determinants of Health Working Group

For the past year, representatives from CDC's Centers, Institutes, and Offices have met to discuss implementation of a social determinants of health research program at CDC/ATSDR. Social determinants of health is a collective term that refers to individual and environmental level social and economic factors - both risk and protective - that affect health. Following identification of social determinants as one of four research priorities during the 1999 EPO research agenda review process, staff from the Evaluation and Behavioral Science Methods Branch, DPRAM, met with members of the Excellence in Science Committee (EISC) to discuss how to approach this as an agency-

Continued on page 4: EPO Workgroups

Informed Consent Guide

An important part of a research protocol is the informed consent statement, which ensures that persons who participate in research have the opportunity to choose whether to participate. It should provide the participants with complete information about the project so that they understand the ramifications of the research, and are able to make an informed decision to participate without coercion and undue influence. Consent forms should not contain exculpatory language "through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

The following information should be included in the informed consent:

- Statement that the study involves research;
- Purposes and procedures;
- Expected duration of the study;
- Description of risks and benefits;
- Disclosure of alternative procedures available;
- Description of confidentiality protection procedures;
- Explanation of whom to contact for questions about the research;
- Explanation of whom to contact for questions about research subject's rights;
- Statement that participation is voluntary;
- Statement that the participant may refuse to take part in the study; and
- Statement that the participant would be able to withdraw at any time during the study without any penalty or loss of benefits to which the subject is otherwise entitled.

If the research is "greater than minimal risk," the following should be added:

- Explanation of whether any compensation is available if injury occurs;
- Explanation of whether any medical treatments are available and what they consist of; and
- Statement of where to obtain further information.

When appropriate, the following six additional elements should be included:

- Explanation that there may be unforeseeable risk by participating in the study;
- Explanation that the subject's participation may be terminated by the investigator without consent;
- Explanation of any additional costs to participant;
- Explanation of the process of withdrawal and any consequences of a subject's decision to withdraw from the study;
- Statement that any significant new findings that may relate to a subject's willingness to continue participation will be provided to the subject, and
- Statement of the approximate number of subjects in the study.

For more details see *EPO Overview of Scientific Procedures* or CDC ADS Website.

IRB Updates

Change in "contact for human subject information" in Informed Consent Forms

Consent forms used in a number of CDC IRB-approved research studies direct potential subjects to contact the Deputy Associate Director for Science if they have questions about their rights as research subjects. As a result of the Human Subject Office's recent transition to a new phone system and away from ASYNC/VoiceCom, the contact information on all of these forms is now out of date. A sample sentence containing the new information is provided below for your use and future reference:

"If you have questions about your rights as a subject in this research study, please call 1-800-584-8814, leave a message including your name and phone number, and someone will call you back as soon as possible."

Since revising consent forms by inserting the correct information listed above is a very minor change, somewhat equivalent to correcting a typo, **a formal amendment (CDC form 0.1252) for this change is not required**. Instead, please either e-mail your revised consent document(s) to the Human Subjects Review-OD mailbox or send hardcopies to mailstop (C25). Include your protocol number and title.

Standards for Privacy of Individually Identifiable Health Information-- implications for public health practice

Congress recognized the need for national patient record privacy standards in 1996 when they enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The law included provisions designed to save money for health-care businesses by encouraging electronic transactions, but it also required new safeguards to protect the security and confidentiality of that information. The law gave Congress until August 21, 1999, to pass comprehensive health privacy legislation. When Congress did not enact such legislation after three years, the law required the Department of Health and Human Services (DHHS) to craft such protections by regulation.

As required by the Privacy Rule, the final regulation covers health plans, health-care clearinghouses, and those health-care providers who conduct certain financial and administrative transactions (e.g., electronic billing and funds transfers) electronically. All medical records and other individually identifiable health information used or disclosed by a covered entity in any form, whether electronically, on paper, or orally, are covered by the final rule.

The Rule explicitly permits sharing of protected health information with public health authorities, for purposes "***including but not limited to***, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions." Sharing with public health may be required by law if specific state provisions require such sharing; the Rule permits but does not require disclosures to public health in other instances (consistent with current practice). In the Rule public health authority is broadly defined. The intent of the Rule was to permit continuation of ongoing public health activities. The document entitled, "Health Insurance Portability and Accountability Act of 1996 (HIPAA)-- Privacy Rule: Provisions relevant to public health practice" contains excerpts from the website of the Office for Civil Rights (OCR) in the United States Department of Health and Human Services and highlights major provisions of the Rule that are relevant to public health practice (see www.cdc.gov/cic under legislation).

Note that requirements and definitions regarding research differ between the Common Rule and the Privacy Rule; HHS is expected to resolve these issues early in 2002. Further information will be forthcoming.

EPO Workgroups: Continued from page 2

wide project. The Social Determinants of Health (SDOH) Working Group was formed to identify what CDC could gain as well as contribute to the (re)emerging emphasis on social factors and health outcomes. The group's findings and recommendations were outlined in a report presented to EISC in March 2001. The WG was asked to elicit comments on the recommendations from CIO leaders. Findings from the CIO meetings were presented to EISC this October, at which point the SDOH WG was encouraged to move forward with steps to implement an SDOH research program at CDC/ATSDR. Recommendations for moving forward include (1) coordination, an activity the WG determined should continue with EPO given EPO's role of providing services to the CIOs; (2) development of education and training opportunities; (3) development or application of scientific methods appropriate to public health research and practice; (4) consultation with external experts; and, (5) dissemination of information and products applicable to SDOH and public health practice.

For information about the SDOH WG, contact the co-chairs: Marilyn Metzler (EPO) at 770-488-8203 or Catlainn Sionean (NCHSTP) at 404-639-1820.

Important Websites

CDC IRB Intranet Websites
http://inside2.od.cdc.gov/adshsp/source/query.asp

CDC ADS Internet Websites
http://www.cdc.gov/od/ads/index.htm

CDC ADS Intranet Websites
http://intranet.cdc.gov/od/ads/index.htm

Office for Human Research Protections
http://ohrp.osophs.dhhs.gov/index.html

Office of Research Integrity
http://www.ori.dhhs.gov/

EPO Internet Websites
http://www.cdc.gov/epo/

EPO Intranet Websites
http://intranet.cdc.gov/epo/home.htm